STUDY PROTOCOL

Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management (OPTIMISM): Protocol for a feasibility randomised controlled trial [version 1; peer review: 4 approved]

Eirini Kontou[1], Marion Walker[1], Shirley Thomas[1], Caroline Watkins[2], Holly Griffiths[1], Miriam Golding-Day[1], Carla Richardson[3], Nikola Sprigg[3]

[1]School of Medicine, Division of Rehabilitation, Ageing & Wellbeing, University of Nottingham, Nottingham, UK
[2]Faculty of Health & Wellbeing, University of Central Lancashire, Preston, UK
[3]School of Medicine, Division of Clinical Neuroscience, University of Nottingham, Nottingham, UK

v1 **First published:** 29 Jun 2020, **2**:24
https://doi.org/10.12688/amrcopenres.12911.1
Latest published: 29 Jun 2020, **2**:24
https://doi.org/10.12688/amrcopenres.12911.1

Abstract

Background: A transient ischaemic attack (TIA) and minor stroke are medical emergencies and often a warning sign of future strokes if remain untreated. Few studies have investigated the long-term psychosocial effects of TIA and minor stroke. Secondary prevention and medical management are often the primary focus with limited access offered for further psychosocial support. Psychoeducational interventions can provide education and advice to people with physical health conditions and, with suitable tailoring, could be appropriate for people after TIA and minor stroke. This study aims to develop a group psychoeducational intervention for people after TIA and minor stroke and to test whether it is acceptable and feasible.
Methods: This mixed-methodology study involves two phases: Phase 1) A qualitative study to determine the content of a suitable intervention; Phase 2) A single-centre feasibility randomised controlled trial to evaluate the acceptability of this intervention. The overall study has ethical approval. Stroke survivors have been involved in designing and monitoring the trial. The aim is to recruit 30-40 participants from a Stroke/TIA Service, within 6 months following their diagnosis. Participants will be randomly allocated to either the usual care control group or the intervention group (psychoeducational programme). The programme will consist of six group sessions based on providing education, psychological and social support. The primary outcomes will relate to the feasibility aims of the study. Outcomes will be collected at 3 and 6 months to assess mood, quality of life, knowledge and satisfaction, and resource use.
Discussion: There is a need to develop and evaluate effective interventions that enhance the education provided to people after TIA

Open Peer Review

Reviewer Status ✓ ✓ ✓ ✓

	Invited Reviewers			
	1	**2**	**3**	**4**
version 1 29 Jun 2020	✓ report	✓ report	✓ report	✓ report

1. **Terry J. Quinn**, University of Glasgow, Glasgow, UK
2. **Suzie Wang**, Leeds Beckett University, Leeds, UK
3. **Grace Turner**, University of Birmingham, Birmingham, UK
4. **Catherine Ford**, University of East Anglia, Norwich, UK

Any reports and responses or comments on the article can be found at the end of the article.

and minor stroke and to promote their psychosocial wellbeing. Findings will indicate the acceptability of the intervention and parameters needed to conduct a definitive trial.
Registration: ClinicalTrials.gov ID NCT02550392; registered on 15 September 2015; status: completed.

Keywords
Transient Ischaemic Attack, Minor Stroke, Group Intervention, Psychoeducation, Feasibility Trial

Corresponding author: Eirini Kontou (eirini.kontou@nottingham.ac.uk)

Author roles: Kontou E: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Walker M**: Funding Acquisition, Methodology, Project Administration, Supervision; **Thomas S**: Funding Acquisition, Methodology, Project Administration, Supervision, Writing – Review & Editing; **Watkins C**: Funding Acquisition, Methodology, Supervision; **Griffiths H**: Investigation, Project Administration, Visualization, Writing – Original Draft Preparation; **Golding-Day M**: Investigation, Writing – Original Draft Preparation; **Richardson C**: Investigation, Project Administration; **Sprigg N**: Methodology, Project Administration, Supervision

Competing interests: No competing interests were disclosed.

Grant information: This study is funded by a Stroke Association Postdoctoral Fellowship for Dr Eirini Kontou (TSA PDF 2015/01).
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: Kontou E, Walker M, Thomas S *et al.* **Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management (OPTIMISM): Protocol for a feasibility randomised controlled trial [version 1; peer review: 4 approved]** AMRC Open Research 2020, **2**:24 https://doi.org/10.12688/amrcopenres.12911.1

First published: 29 Jun 2020, **2**:24 https://doi.org/10.12688/amrcopenres.12911.1

Abbreviations

OPTIMISM, Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management; CRN, Clinical Research Network; GCP, Good Clinical Practice; GP, General Practitioner; HRA, Health Research Authority; NHS, National Health Service; PPI, Patient and Public Involvement; R&D, Research & Development; RCT, Randomised Controlled Trial; REC, Research Ethics Committee; TIA, Transient Ischaemic Attack.

Introduction

Background and rationale

A transient ischaemic attack (TIA), also referred to as a 'mini-stroke', is characteristically a brief and sudden episode of focal neurological dysfunction with clinical symptoms that typically resolve completely within 24 hours[1]. A 'minor stroke' is a term used for stroke patients with mild and non-disabling symptoms, but there is considerable variation between studies in the criteria used to define a minor stroke[2]. The National Institute of Health Stroke Scale is often used to define a minor stroke as a score of ≤3 at the time of initial assessment[3].

More than half of all cases of stroke are patients who have experienced a TIA or minor stroke[4] and considered high risk for a subsequent major stroke. Typically, it is assumed that TIA and minor stroke patients are expected to make a full recovery and to experience only minimal or no functional deficits[5]. However, the Stroke Association has recently published a brief report stating that around 70% of people with a TIA had reported long-term effects (i.e., memory loss, poor mobility, problems with speech and understanding) and 60% of people reported having been affected emotionally by their TIA experience[6].

To date, very few studies have addressed the long-term impact of TIA and minor stroke, but evidence suggests that patients report experiences of certain psychosocial difficulties affecting their quality of life[7–9]. Currently, secondary prevention is the predominant focus of TIA management, and patients presenting with no visible or minor impairments are not typically offered rehabilitation follow-up support or access to multidisciplinary stroke services[10–12].

Emerging evidence suggests that the psychosocial effects of TIA and minor stroke often remain unrecognised and untreated. Psychosocial effects such as anxiety, depression and anger have been investigated[13–16], but only a few studies have actually looked at these emotional effects post-TIA[17–20]. Regarding the risk of depression post-TIA, some studies have found a similar association following a stroke[21,22]. It has been reported that TIA patients have similarly high rates of depression (21%) and anxiety (29%) as those with stroke from a large regional stroke registry study[23]. Findings from recent systematic reviews report TIA patients and minor stroke patients may experience residual effects such as depression, fatigue and cognitive difficulties[24,25] and anxiety[26]. Typical emotional difficulties described by TIA patients have been sadness, frustration, worries for an uncertain future and loss of confidence[27,28].

Psychosocial difficulties can significantly affect the quality of life for those following a TIA or minor stroke[29] and patients are less likely to adhere to secondary prevention precautions. A qualitative study[30] found that the experience of a TIA can reduce individuals' quality of life despite the short-term nature of their symptoms. Recently, a service evaluation published findings suggesting that there was a considerably high proportion of TIA and minor stroke patients with clinically significant levels of depression and anxiety compared to a healthy control group[31]. Programmes that have included healthy lifestyle counselling and exercise for cardiac rehabilitation have shown to be beneficial and could potentially be adapted for TIA and stroke patients[32,33].

Despite some encouraging evidence to promote emotional well-being for people after stroke[34,35], it continues to remain unclear what support could be offered to reduce distress and to promote adherence to secondary prevention. To date there have been no studies that have designed and tested an intervention offering education to address psychosocial difficulties following a TIA and minor stroke.

According to the NHS Improvement Stepped Care Model for Psychological Care in Stroke[36], using a time-limited intervention could potentially allow a large number of individuals to access appropriate services which could improve their quality of life and stroke rehabilitation outcomes. Self-help leaflets, support groups, signposting, provision of information and other low-level interventions may be considered more appropriate for adjusting to a TIA/minor stroke diagnosis[37,38]. A demand for low-level interventions within physical healthcare settings has been increasing since the National Institute of Clinical Excellence recommendations for Improving Access in Psychological Therapies[39].

Access to these interventions are currently limited and mainly targeted at patients with mental health problems. For an intervention to be affective and suitable for TIA and minor stroke survivors, content and delivery will require tailoring towards their needs.

Psychoeducation is a potential approach which necessitates the provision of information and self-help strategies that can empower individuals to manage and cope with their difficulties[40]. Psychoeducational interventions have already been effectively delivered in patients with physical illnesses[40], and in stroke family caregivers[41]. Such interventions can be brief and delivered in a group setting to address cost-effectiveness and social support[42]. This evidence justifies greater focus on the psychosocial impact of TIA/minor stroke and development of an appropriate intervention.

Research aim and objectives

The aim of this research is to develop a time-limited psychoeducational intervention that can be delivered in a group format for people with TIA and minor stroke and to evaluate the acceptability and feasibility of a randomised controlled trial (RCT). A qualitative study with people after TIA/minor stroke

and expert clinicians and researchers will be initially conducted to help develop the psychoeducational intervention (Phase 1). This protocol mainly describes the single-centre feasibility RCT (Phase 2) to determine the acceptability of the proposed intervention and the parameters to design a definitive trial.

Primary objective. The primary objective is to determine whether it is feasible to conduct a RCT to evaluate a group psychoeducational intervention for people after TIA and minor stroke.

Secondary objectives. The secondary objectives are to test the integrity of the study protocol, such as the methods of data collection, randomisation procedures and the blinding of independent assessors.

- Can we identify participants willing to be randomised?
- Consent and drop-out rates
- Appropriateness of inclusion/exclusion criteria
- Can we deliver the intervention as planned?

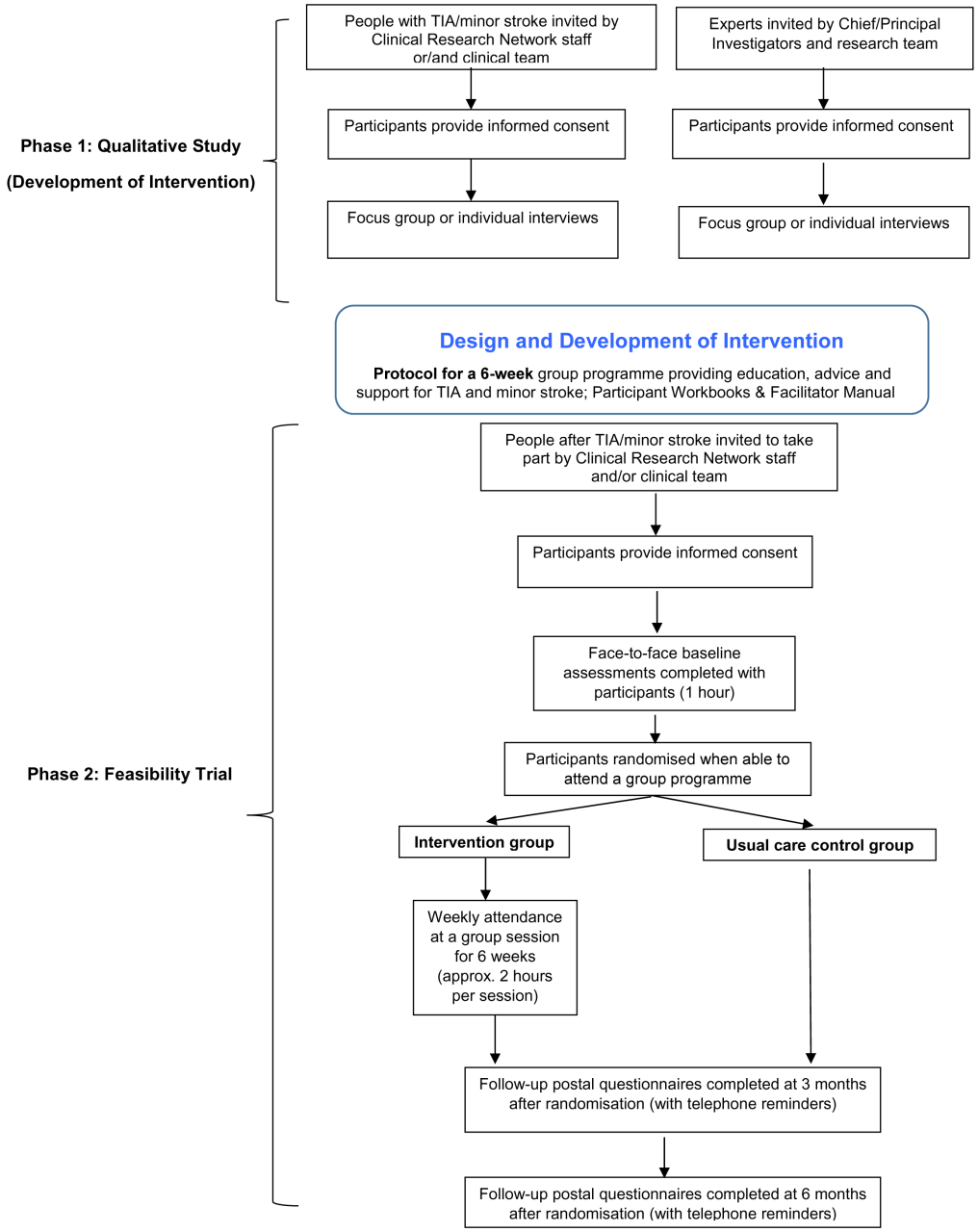

Figure 1. OPTIMISM Study Flowchart.

- Can we retain participants in the study?
- What are the most relevant outcome measures?

Methods and analysis

Study design and setting

The OPTIMISM study has two distinct phases. Phase 1 (Qualitative Study), outlined in Figure 1, focused on the development of the intervention. Phase 2 (Feasibility Trial), described here in further detail, focuses on delivering the intervention within a single-centre feasibility RCT. The feasibility trial protocol methods adhere to the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) guidelines for the reporting of study protocols[43] (see *Reporting guidelines*).

The feasibility RCT is a parallel group, two-arm trial with a 1:1 allocation ratio of a group-based psychoeducational intervention versus a usual care control. We will adhere to the recommendations and ethical considerations proposed by the Standard Protocol Items for Randomized Trials (SPIRIT)[43] statement guidelines. Participants will be people diagnosed with TIA and minor stroke recruited from a Stroke/TIA Service.

Participants

The timeline and proposed flow of participants through the feasibility trial (Phase 2) is shown in Figure 1. Participant information materials are available as Extended data[44].

The inclusion criteria are as follows:

- Aged 18 years or over
- Have a confirmed diagnosis of first or recurrent TIA or minor stroke
- Are independent with activities of daily living after diagnosis
- Are identified within 6 months following diagnosis of TIA or minor stroke
- Able to provide informed consent

Exclusion criteria are as follows:

- Are not able to communicate in English
- Have a diagnosis of dementia prior to the TIA/minor stroke that would impact their ability to complete baseline questionnaires and to participate in group sessions (based on self-report by patient/carer and subsequently confirmed by checking medical records).
- Are receiving psychological interventions for mental health problems immediately prior to their diagnosis of TIA/minor stroke.
- Have visual (blindness) or auditory (deafness) impairments that would impact on their ability to complete baseline questionnaires.
- Have cognitive or communication difficulties that would impact on their ability to complete baseline questionnaires and to participate in group sessions.

Intervention development

Phase 1 (Qualitative Study) will involve focus groups or individual interviews to explore the views of both people with TIA/minor stroke and experts working clinically or conducting research with people with TIA/minor stroke. Service users and experts will be asked to highlight the most important difficulties faced after TIA and minor stroke. A topic guide with open-ended questions will be used to guide the interview process. Data collection and sample size will be determined by saturation in themes identified. Results will be analysed using thematic analysis to determine the content of an intervention for people after TIA and minor stroke.

The intervention will be focused on providing education, advice and support within the first six months following a TIA and/or minor stroke diagnosis. It will be designed to help individuals to identify knowledge and skills to promote adjustment, coping and healthier lifestyles.

For each session there will be a presentation containing information about a topic and activities to aid group discussion. Each session will be facilitated by visual aids such as presentation slides and flipcharts. The topics will be shaped by findings from the Phase 1 Qualitative Study. Activities during and in-between group sessions will be introduced to encourage participants to practice and skills learnt.

Participant workbooks for each session and a facilitator workbook for the group programme will be developed by the research team (see Figure 1). These workbooks will support the intervention delivery and will be further developed after the end of the feasibility trial. The OPTIMISM group intervention programme will be described based on the Template for Intervention Description and Replication (TIDieR) checklist[45] (see *Reporting guidelines*).

Intervention and comparator

Participants will be randomised after consent and baseline assessments to the intervention or usual care control.

- *Control group:* Usual care including all services routinely available to them.
- *Intervention group:* Usual care plus a group intervention based on a psychoeducational framework. This programme will be offered in 6 sessions over 2 months. Sessions will be delivered face to face in a small group of participants. The intervention will be delivered in a suitable place according to the availability of space and access for participants. It will be facilitated by an assistant psychologist or a trained professional with matched skills and competences to deliver low-level group interventions. The group facilitator will receive further training from members of the research team responsible for the development of the intervention. Each session will last approximately 2 hours and will include a 15-minute comfort break with refreshments, which will allow participants to socialise. Each session will focus on providing information about different topics and on developing problem-solving skills to cope with physical and psychosocial difficulties following a TIA or minor stroke.

Outcomes

Primary outcome measures will mainly pertain to the feasibility aims of the study. Specifically, we are testing the feasibility of the trial and the tolerability and acceptability of delivering the intervention, study attrition, completing the trial and collecting valid and reliable data. This will be with the aim to determine the key parameters for conducting a larger definitive trial. The feasibility outcome measures are:

- Feasibility of recruiting TIA and minor stroke patients to a group psychoeducational intervention (rates of cognitive/mood difficulties, stroke severity, recruitment, providing consent, completing intervention, and returning outcome questionnaires).
- Recruitment and exclusion rates (how many patients eligible, approached and how many consented, or excluded).
- Completion rates for those who entered into the trial (how many completed the intervention/number of sessions attended, how many completed and returned the follow-up assessments by post, how many follow-up assessments required telephone reminders and/or face-to-face appointment).

At baseline we will collect sociodemographic details of participants including age, gender, ethnicity, employment, living arrangements and any relevant medical information (e.g., type of stroke, stroke classification etc).

Measures to be completed face-to-face at baseline after informed consent:

- TIA/stroke severity (NIHSS)[46]
- Cognition (Oxford Cognitive Screen (OCS))[47]
- Mood (General Health Questionnaire (GHQ-30); Patient Health Questionnaire-2 (PHQ-2))[48,49]
- Quality of life (EuroQuol-5D-5L (EQ-5D))[50]
- Knowledge & feedback questionnaire based on one previously published[51]
- Resource Use questionnaire

Measures to be completed by post at 3 and 6 months after randomisation:

- Mood (GHQ-30; PHQ-2)
- Quality of Life (EQ-5D-5L)
- Knowledge & feedback questionnaire
- Resource use questionnaire

Sample size and recruitment strategy

For the qualitative study (Phase 1), a minimum of 10 people with TIA or minor stroke and at least six experts will be interviewed. The sample size will be determined by data saturation in themes. For the feasibility trial (Phase 2) no formal sample size is required. However, a sample size of 30 patients or greater is considered adequate to estimate key parameters to inform the design of a definite trial[52,53]. We aim to recruit a sample size of 30–40 participants (n=15–20 per group). Recruitment difficulties may affect progress and sample size; however, the research team has extensive experience in conducting feasibility trials.

The trial opened for recruitment in July 2018 and will be open for recruitment until June 2019. Participants will be enrolled into the study by a member of staff from the Clinical Research Network (CRN) or a member of the research team. The CRN/research staff will visit the Stroke wards and TIA clinics to provide information about trial to potential participants. If they wish to take part, then their permission will be sought to be contacted again by the CRN/research team. A pre-paid envelope will be provided to anyone who wish to return a reply slip with their contact details by post.

The process for obtaining participant informed consent will be in accordance with the Research Ethics Committee (REC) guidance, and Good Clinical Practice (GCP). Following a full explanation of the study, the participant will be required to provide informed written consent before they can participate. Model consent materials are available as *Extended data*[44].

Randomisation procedure and blinding

Randomisation to each arm on a 1:1 basis and once there are 8–12 individuals who have consented and who are able to attend the same therapy group (should they be randomised to receive it). Randomisation will be conducted using a computer-generated randomisation list that will be held on a secure server and overseen by an independent member of the research team.

It is not possible for the participants or person delivering the intervention to be blind to the group allocation. The researchers completing outcome assessments at 3 and 6 months after randomisation will be blinded and will not be involved in any other aspect of the trial.

Data collection, management and analysis

Data will be collected on a paper-based data collection form designed specifically for each phase of the study and will subsequently be entered onto a secure electronic database. Each participant will be assigned a trial identity code number for use on study documents and databases.

When data collection is completed, a data quality check will be conducted, and the proportion of missing items will be examined. Analysis of the outcome data will be conducted on an intention to treat basis and will be presented using summary statistics. Any differences between the two arms will be calculated at baseline and 6-month follow-up, along with 95% confidence intervals. The findings will be used to inform power and sample size calculations for a future definitive study and to determine appropriateness of these measures. All study data will be kept strictly confidential and stored in a secure and locked office, and on password-protected databases.

Feasibility of completing the intervention

In order to assist in assessing acceptability of the intervention we will provide all the intervention participants with a feedback questionnaire during their final session to gather information on appropriateness of timing, duration and frequency of sessions.

Tolerability will be captured by the proportion of participants who withdraw or decline the intervention or any sessions and the reasons for this. Any adverse events apportioned to be as a result of participating in the intervention will be reported.

The integrity of the study protocol will be examined by how many participants complete the study, percentage of missing data, percentage of people who complete questionnaires, percentage of people who complete each outcome measure at 3- and 6-month follow-ups, and calculation of the cost of running the study.

PPI

PPI is integrated in all stages of the project, including for example the design and conduct of the intervention and suggestions in relation to all study materials. During Phase 1, PPI will be utilised to establish whether the study is both feasible and practical and whether the choice of the proposed intervention is something that would be well received by participants. PPI will also contribute to the dissemination of research findings. By choosing to include PPI in the research process we will ensure that the information provided to the study participants is user friendly, informative and written in lay language. This will help to enhance the recruitment and retention of participants to different stages of the project.

Ethics and dissemination

The study is approved by the UK NHS Health Research Authority (East Midlands- Nottingham 1 Research Ethics Committee, ref 15/EM/0453) and the Research & Development department of the NHS participating site. This paper reports on the study protocol version 4.0, dated 17th May 2018. We will conduct our study in line with the Declaration of Helsinki[54] and according to the principles of GCP[55]. The sponsor for this study is the University of Nottingham, King's Meadow Campus, Nottingham, UK.

Any important protocol amendments will be reported to the Health Research Authority, will be registered at ClinicalTrials.gov and will be communicated to the participating site and study sponsor. A Trial Steering Committee with independent members will meet to assist in guiding and supervising the project team.

Participants will be informed that they are free to withdraw at any time without affecting their future care. Any data collected before their withdrawal may still be used in analysis. For participants who cannot attend all group intervention sessions, this will be recorded as an outcome. However, they will still be asked if they do not wish to receive the postal outcome measures. The occurrence of adverse events as a result of participation within this study is not expected, since the trial only involves a low risk psychological intervention that will be designed to improve outcomes and ease distress, and therefore no adverse event data shall be collected. If a participant is identified as suicidal, then their GP will be informed and the usual clinical procedures will be followed by their clinical team.

We plan to disseminate our findings by presenting results at national and international stroke and rehabilitation conferences. The RCT results will also be submitted for publication to an international, peer-reviewed journal. We will provide trial participants with a lay summary of the findings at the end of the study if requested. Findings may be further publicised by the university, hospital, funder websites and publications.

Trial status

Recruitment on the participating site closed on 30th June 2019 and the overall trial was completed on 31st January 2020.

Data availability

Underlying data

No underlying data are associated with this study.

Extended data

Figshare: Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management (OPTIMISM): Protocol for a Feasibility Randomised Controlled Trial. https://doi.org/10.6084/m9.figshare.c.5019200.v1[44]

This project contains the following extended data:

- OPTIMISM Research Protocol v4.0, dated 17.05.18
- OPTIMISM Phase 2 Participant Information Sheet v3.0, dated 17.05.18
- OPTIMISM Phase 2 Participant Consent Form v3.0, dated 17.05.18
- OPTIMISM Phase 2 Poster Information Leaflet v1.0, dated 09.11.15
- OPTIMISM Invitation Reply Slip v1.0, dated 21.09.15
- OPTIMISM Intervention Outline v2.0, dated 17.05.18

The OPTIMISM participant or facilitator workbooks are not currently available publicly as the trial results are not yet published. For further details regarding the content of the intervention, please contact the corresponding author (eirini.kontou@nottingham.ac.uk).

Reporting guidelines

SPIRIT Checklist for Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management (OPTIMISM): Protocol for a Feasibility Randomised Controlled Trial. https://doi.org/10.6084/m9.figshare.c.5019200.v1[44].

TIDieR Checklist for Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management

(OPTIMISM): Protocol for a Feasibility Randomised Controlled Trial. https://doi.org/10.6084/m9.figshare.c.5019200.v1[44].

Authors' Contributions

EK is the chief investigator for the study. HG has delivered the intervention. MGD has assisted with the data collection for the study and in the drafting of the manuscript. NS is the principal investigator at the participating NHS site and a collaborator. ST, CW, MW are co-investigators. CR is the lead recruiting officer at participating site.

All authors have read and approved the final manuscript.

Acknowledgements

We are grateful to the Stroke Association for funding this project as part of a postdoctoral fellowship. We would like to thank the Clinical Research Team at Nottingham University Hospitals for their support with recruitment. We would also like to thank the stroke survivors who have assisted with the development of the intervention and those who have taken part. Additional thanks to Abigail Lee for her help with the formatting of the submitted manuscript.

References

1. Royal College of Physicians: **Diagnosis and initial management of TIA**. London: Royal College of Physicians, 2010.
2. Crespi V, Braga M, Beretta S, *et al.*: **A practical definition of minor stroke.** *Neurol Sci.* 2013; **34**(7): 1083–6.
PubMed Abstract | Publisher Full Text
3. Fischer U, Baumgartner A, Arnold M, *et al.*: **What is a minor stroke?** *Stroke.* 2010; **41**(4): 661–6.
PubMed Abstract | Publisher Full Text
4. Verbraak ME, Hoeksma AF, Lindeboom R, *et al.*: **Subtle problems in activities of daily living after a transient ischemic attack or an apparently fully recovered non-disabling stroke.** *J Stroke Cerebrovasc Dis.* 2012; **21**(2): 124–30.
PubMed Abstract | Publisher Full Text
5. Green TL, King KM: **Functional and psychosocial outcomes 1 year after mild stroke.** *J Stroke Cerebrovasc Dis.* 2010; **19**(1): 10–16.
PubMed Abstract | Publisher Full Text
6. Stroke Association: **Not just a funny turn: The real impact of TIA. Stroke Association Campaign Briefing Report.** London: Stroke Association, 2014.
Reference Source
7. Daffertshofer M, Mielke O, Pullwitt A, *et al.*: **Transient ischemic attacks are more than "ministrokes".** *Stroke.* 2004; **35**(11): 2453–8.
PubMed Abstract | Publisher Full Text
8. Adamit T, Maeir A, Ben Assayag E, *et al.*: **Impact of first-ever mild stroke on participation at 3 and 6 month post-event: the TABASCO study.** *Disabil Rehabil.* 2015; **37**(8): 667–73.
PubMed Abstract | Publisher Full Text
9. Luengo-Fernandez R, Gray AM, Bull L, *et al.*: **Quality of life after TIA and stroke: ten-year results of the Oxford Vascular Study.** *Neurology.* 2013; **81**(18): 1588–95.
PubMed Abstract | Publisher Full Text | Free Full Text
10. National Institute for Health and of Clinical Excellence: **Stroke: Diagnosis and management of acute stroke and transient ischaemic attack (TIA).** London: NICE, 2008.
Reference Source
11. Fens M, van Heugten CM, Beusmans GHMI, *et al.*: **Not as transient: patients with transient ischaemic attack or minor stroke experience cognitive and communication problems; an exploratory study.** *Eur J Gen Prac.* 2013; **19**(1): 11–6.
PubMed Abstract | Publisher Full Text
12. Terrill AL, Schwartz JK, Belagaje SR: **Best Practices for The Interdisciplinary Rehabilitation Team: A Review of Mental Health Issues in Mild Stroke Survivors.** *Stroke Res Treat.* 2018; **2018**: 618738.
PubMed Abstract | Publisher Full Text | Free Full Text
13. Kneebone II, Lincoln NB: **Psychological problems after stroke and their management: state of knowledge.** *Neurosci Med.* 2012; **3**(01): 83–9.
Publisher Full Text
14. Morsund ÅH, Ellekjær H, Gramstad A, *et al.*: **Cognitive and Emotional Impairment after Minor Stroke and Non-ST-Elevation Myocardial Infarction (NSTEMI): A Prevalence Study.** *Stroke Res Treat.* 2019; **2019**: 2527384.
PubMed Abstract | Publisher Full Text | Free Full Text
15. Blöchl M, Meissner S, Nestler S: **Does depression after stroke negatively influence physical disability? A systematic review and meta-analysis of longitudinal studies.** *J Affect Disord.* 2019; **247**: 45–56.
PubMed Abstract | Publisher Full Text
16. Unsworth DJ, Mathias JL, Dorstyn DS: **Preliminary Screening Recommendations for Patients at Risk of Depression and/or Anxiety more than 1 year Poststroke.** *J Stroke Cerebrovasc Dis.* 2019; **28**(6): 1519–28.
PubMed Abstract | Publisher Full Text
17. McHutchison CA, Cvoro V, Makin S, *et al.*: **Functional, cognitive and physical outcomes 3 years after minor lacunar or cortical ischaemic stroke.** *J Neurol Neurosurg Psychiatry.* 2019; **90**(4): 436–43.
PubMed Abstract | Publisher Full Text | Free Full Text
18. Sackley CM, Mant J, McManus RJ, *et al.*: **Functional and emotional outcomes after transient ischemic attack: A 12-month prospective controlled cohort study.** *Int J Stroke.* 2019; **14**(5): 522–529.
PubMed Abstract | Publisher Full Text
19. Moran GM, Calvert M, Feltham MG, *et al.*: **A retrospective cohort study to investigate fatigue, psychological or cognitive impairment after TIA: protocol paper.** *BMJ Open.* 2015; **5**(4): e008149.
PubMed Abstract | Publisher Full Text | Free Full Text
20. Croot EJ, Ryan TW, Read J, *et al.*: **Transient ischaemic attack: a qualitative study of the long term consequences for patients.** *BMC Fam Pract.* 2014; **15**(1): 174.
PubMed Abstract | Publisher Full Text | Free Full Text
21. El Husseini N, Goldstein LB, Peterson ED, *et al.*: **Depression and antidepressant use after stroke and transient ischemic attack.** *Stroke.* 2012; **43**(6): 1609–16.
PubMed Abstract | Publisher Full Text
22. Luijendijk HJ, Stricker BH, Wieberdink RG, *et al.*: **Transient ischemic attack and incident depression.** *Stroke.* 2011; **42**(7): 1857–61.
PubMed Abstract | Publisher Full Text
23. Broomfield NM, Quinn TJ, Abdul-Rahim AH, *et al.*: **Depression and anxiety symptoms post-stroke/TIA: prevalence and associations in cross-sectional data from a regional stroke registry.** *BMC Neurol.* 2014; **14**: 198.
PubMed Abstract | Publisher Full Text | Free Full Text
24. Moran GM, Fletcher B, Feltham MG, *et al.*: **Fatigue, psychological and cognitive impairment following transient ischaemic attack and minor stroke: a systematic review.** *Eur J Neurol.* 2014; **21**(10): 1258–67.
PubMed Abstract | Publisher Full Text
25. Cai W, Mueller C, Li YJ, *et al.*: **Post stroke depression and risk of stroke recurrence and mortality: A systematic review and meta-analysis.** *Ageing Res Rev.* 2019; **50**: 102–9.
PubMed Abstract | Publisher Full Text
26. Rafsten L, Danielsson A, Sunnerhagen KS: **Anxiety after stroke: a systematic review and meta-analysis.** *J Rehabil Med.* 2018; **50**(9): 769–78.
PubMed Abstract | Publisher Full Text
27. Spurgeon L, James G, Sackley C: **Subjective experiences of transient ischaemic attack: a repertory grid approach.** *Disabil Rehabil.* 2013; **35**(26): 2205–12.
PubMed Abstract | Publisher Full Text
28. Crowfoot G, van der Riet P, Maguire J: **Real-life Experiences of People With Transient Ischaemic Attack or Minor Stroke: A Qualitative Literature Review.** *J Clin Nurs.* 2018; **27**(7–8): 1381–98.
PubMed Abstract | Publisher Full Text
29. Sangha RS, Caprio FZ, Askew R, *et al.*: **Quality of life in patients with TIA and minor ischemic stroke.** *Neurology.* 2015; **85**(22): 1957–63.
PubMed Abstract | Publisher Full Text | Free Full Text
30. Gibson J, Watkins C: **People's experiences of the impact of transient ischaemic attack and its consequences: qualitative study.** *J Adv Nurs.* 2012; **68**(8): 1707–15.
PubMed Abstract | Publisher Full Text
31. Kellett N, Drummond AE, Palmer T, *et al.*: **Impact of transient ischaemic attack and minor stroke on daily life.** *Int J Ther Rehabil.* 2014; **21**(7): 318–23.
Publisher Full Text
32. Ellis H, Ahmed T, Khanna P: **Life after stroke and transient ischaemic attack.** *GM Journal.* 2011; **41**: 413.
Reference Source
33. Lennon O, Blake C: **Cardiac rehabilitation adapted to transient ischaemic attack**

and stroke (CRAFTS): a randomised controlled trial. *BMC Neurol.* 2009; **9**(1): 9.
PubMed Abstract | Publisher Full Text | Free Full Text

34. Majumdar S, Morris R: **Brief group-based acceptance and commitment therapy for stroke survivors.** *Br J Clin Psychol.* 2019; **58**(1): 70–90.
PubMed Abstract | Publisher Full Text

35. Kirkevold M, Bragstad LK, Bronken BA, *et al.*: **Promoting psychosocial well-being following stroke: study protocol for a randomized, controlled trial.** *BMC Psychol.* 2018; **6**(1): 12.
PubMed Abstract | Publisher Full Text | Free Full Text

36. NHS Stroke Improvement: **Psychological Care after Stroke: Improving Stroke Service for people with mood and cognitive disorders**. 2012.
Reference Source

37. Turner GM, Backman R, McMullan C, *et al.*: **Establishing research priorities relating to the long-term impact of TIA and minor stroke through stakeholder-centred consensus.** *Res Involv Engagem.* 2018; **4**: 2.
PubMed Abstract | Publisher Full Text | Free Full Text

38. Faux SG, Arora P, Shiner CT, *et al.*: **Rehabilitation and education are underutilized for mild stroke and TIA sufferers.** *Disabil Rehabil.* 2018; **40**(12): 1480–4.
PubMed Abstract | Publisher Full Text

39. Department of Health: **Talking therapies: A four-year plan of action**. 2011.
Reference Source

40. Lukens EP, McFarlane WR: **Psychoeducation as evidence-based practice: Considerations for practice, research, and policy**. In: Roberts AR, Yeager KR, eds. *Foundations of evidence-based social work practice.* Oxford: Oxford University Press, 2006; 291–313.
Reference Source

41. Cheng HY, Chair SY, Chau JP: **The effectiveness of psychosocial interventions for stroke family caregivers and stroke survivors: a systematic review and meta-analysis.** *Patient Educ Couns.* 2014; **95**(1): 30–44.
PubMed Abstract | Publisher Full Text

42. Rodgers M, Asaria M, Walker S, *et al.*: **The clinical effectiveness and cost-effectiveness of low-intensity psychological interventions for the secondary prevention of relapse after depression: a systematic review.** *Health Technol Assess.* 2012; **16**(28): 1–130.
PubMed Abstract | Publisher Full Text | Free Full Text

43. Chan AW, Tetzlaff JM, Gøtzsche PC, *et al.*: **SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials.** *BMJ.* 2013; **346**: e7586.
PubMed Abstract | Publisher Full Text | Free Full Text

44. Kontou E, Walker M, Thomas S, *et al.*: **Optimising Psychoeducation for Transient Ischaemic Attack and Minor Stroke Management (OPTIMISM): Protocol for a Feasibility Randomised Controlled Trial.** *figshare.* Collection. 2020.
http://www.doi.org/10.6084/m9.figshare.c.5019200.v1

45. Hoffmann TC, Glasziou PP, Boutron I, *et al.*: **Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide.** *BMJ.* 2014; **348**: g1687.
PubMed Abstract | Publisher Full Text

46. National Institute of Health: **NIH Stroke Scale International**.
Reference Source

47. Demeyere N, Riddoch MJ, Slavkova ED, *et al.*: **The Oxford Cognitive Screen (OCS): Validation of a stroke-specific short cognitive screening tool.** *Psychol Assess.* 2015; **27**(3): 883–94.
PubMed Abstract | Publisher Full Text

48. Goldberg DP, Hillier VF: **A scaled version of the General Health Questionnaire.** *Psychol Med.* 1979; **9**(1): 139–45.
PubMed Abstract | Publisher Full Text

49. Kroenke K, Spitzer RL, Williams JB: **The Patient Health Questionnaire-2: validity of a two-item depression screener.** *Med Care.* 2003; **41**(11): 1284–92.
PubMed Abstract | Publisher Full Text

50. EuroQol Group: **EuroQol-a new facility for the measurement of health-related quality of life.** *Health Policy.* 1990; **16**(3): 199–208.
PubMed Abstract | Publisher Full Text

51. Lincoln NB, Francis VM, Lilley SA, *et al.*: **Evaluation of a stroke family support organiser: a randomized controlled trial.** *Stroke.* 2003; **34**(1): 116–21.
PubMed Abstract | Publisher Full Text

52. Lancaster GA, Dodd S, Williamson PR: **Design and analysis of pilot studies: recommendations for good practice.** *J Eval Clin Pract.* 2004; **10**(2): 307–12.
PubMed Abstract | Publisher Full Text

53. Hertzog MA: **Considerations in determining sample size for pilot studies.** *Res Nurs Health.* 2008; **31**(2): 180–91.
PubMed Abstract | Publisher Full Text

54. World Medical Association: **World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects.** *Bull World Health Organ.* 2001; **79**(4): 373–374.
PubMed Abstract | Free Full Text

55. **International Council for Harmonisation: Guideline for good clinical practice.** *J Postgrad Med.* 2001; **47**(3): 199–203.
PubMed Abstract

Open Peer Review

Current Peer Review Status: ✔ ✔ ✔ ✔

Version 1

Reviewer Report 27 July 2020

https://doi.org/10.21956/amrcopenres.13981.r26514

✔ **Catherine Ford**

Department of Clinical Psychology and Psychological Therapies, Norwich Medical School, Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, UK

Summary of Paper:

- This paper describes the protocol for a completed two-stage study comprising the development (phase I) and single centre feasibility randomised controlled trial (phase II) of a 12-hour, psycho-education intervention over two months, for groups of people with TIA or minor strokes. The first phase of the research was a qualitative study to develop materials for the psychoeducation group from thematic analysis of focus group data from people with TIA or minor stroke and experts in the field. The second phase of the study, the main focus of the paper, tested the feasibility of the psychoeducation group and a full trial comparing the impact of the group to treatment as usual, on measures of knowledge, mood, quality of life and resource usage.

Study Rationale and Objectives:

- The rationale and objectives for the study are clearly described. This is an important area for research as TIA and minor strokes are estimated to affect 15–83 patients per 100 000 population globally (Barton *et al.*, 2017[1]) with 18-20% risk of stroke within 90 days (Gommans *et al.*, 2009[2]; Heron *et al.*, 2017[3]) and residual difficulties with fatigue, cognition, communication and mood reported (Moran *et al.*, 2014[4]). Although psychoeducation interventions have been found to benefit stroke survivors and caregivers (Cheng *et al.*, 2018 [5]; Ostwald *et al.*, 2014[6]) research has previously been lacking on the potential benefits of psychoeducation for people after TIA or minor stroke.

Design:

- The study is well-designed and clearly reported. The paper outlines the trial design (parallel groups), randomisation (independently overseen computer generated randomisation), allocation ratio (1:1), blinding (outcome assessment) and the process for testing fidelity to the intervention.

- It will be good to understand what constitutes treatment as usual (e.g. hours of input, from

whom, and to what extent this includes support and education) in the report of the study findings.

Methods:

- Sufficient details of the methods are provided in the paper and additional information to allow replication of the feasibility trial. Eligibility criteria, consent process, measures used, timepoints (before, 3 and 6 months after, randomisation) and group size, frequency and duration are all outlined clearly.

- In the report on the findings of the feasibility trial, more information on recruitment and the setting and which locations' data were collected will be helpful.

- The eligibility criteria permitted the feasibility of a trial to be tested without confounding findings with significant sensory, cognitive or communication disorders or mental health difficulties requiring treatment immediately prior to TIA or minor stroke. As cognitive and communication difficulties are found after TIA or minor stroke (Moran *et al.*, 2014[4]) and serious mental illness is associated with cardiovascular risk (Correll *et al.*, 2017[7]) it will be of interest at a later point, to know if and how the intervention can be adapted for a broader client group.

- The measures selected are reliable, valid and cover a range of clinically important outcomes. If possible, the addition of medication adherence to the full trial would be very helpful, given the population targeted and their risk of stroke. Many of the measures, though unfortunately not the GHQ-30, are freely available, which will be important for wider implementation should the intervention be supported by the subsequent full trial.

Datasets:

- As this is a study protocol, no datasets are presented.

References

1. Barton P, Sheppard JP, Penaloza-Ramos CM, Jowett S, et al.: When has service provision for transient ischaemic attack improved enough? A discrete event simulation economic modelling study.*BMJ Open*. 2017; **7** (11): e018189 PubMed Abstract | Publisher Full Text
2. Gommans J, Barber PA, Fink J: Preventing strokes: the assessment and management of people with transient ischaemic attack.*N Z Med J*. 2009; **122** (1293): 3556 PubMed Abstract
3. Heron N, Kee F, Cardwell C, Tully MA, et al.: Secondary prevention lifestyle interventions initiated within 90 days after TIA or 'minor' stroke: a systematic review and meta-analysis of rehabilitation programmes.*Br J Gen Pract*. 2017; **67** (654): e57-e66 PubMed Abstract | Publisher Full Text
4. Moran GM, Fletcher B, Feltham MG, Calvert M, et al.: Fatigue, psychological and cognitive impairment following transient ischaemic attack and minor stroke: a systematic review.*Eur J Neurol* . 2014; **21** (10): 1258-67 PubMed Abstract | Publisher Full Text
5. Cheng HY, Chair SY, Chau JPC: Effectiveness of a strength-oriented psychoeducation on caregiving competence, problem-solving abilities, psychosocial outcomes and physical health among family caregiver of stroke survivors: A randomised controlled trial.*Int J Nurs Stud*. 2018; **87**: 84-93 PubMed Abstract | Publisher Full Text
6. Ostwald SK, Godwin KM, Cron SG, Kelley CP, et al.: Home-based psychoeducational and mailed information programs for stroke-caregiving dyads post-discharge: a randomized trial.*Disabil*

Rehabil. 2014; **36** (1): 55-62 PubMed Abstract | Publisher Full Text
7. Correll CU, Solmi M, Veronese N, Bortolato B, et al.: Prevalence, incidence and mortality from cardiovascular disease in patients with pooled and specific severe mental illness: a large-scale meta-analysis of 3,211,768 patients and 113,383,368 controls.*World Psychiatry*. 2017; **16** (2): 163-180 PubMed Abstract | Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Clinical psychology / neuropsychology of stroke

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 24 July 2020

https://doi.org/10.21956/amrcopenres.13981.r26512

Grace Turner
Centre for Patient Reported Outcomes Research, Institute of Applied Health Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

Summary of article:

- This paper describes the protocol for a qualitative study and feasibility study; the manuscript mostly focuses on the latter. The population of interest is TIA/minor stroke patients and the research aims to address the lack of psychosocial support for these patients through a group psychoeducational intervention. The purpose of the qualitative study is to collect data to inform the content of the intervention. The feasibility study aims to investigate the feasibility/acceptability of the psychoeducational intervention through a single-centre randomised controlled trial design.

Is the rationale for, and objectives of, the study clearly described?

- Yes, the need for an intervention is clearly described with supporting research cited. Although psychoeducation is briefly described, it would be useful to have more information about what psychoeducation is and why it was chosen as the theory to underpin the intervention.

- The objectives for the feasibility study are clearly described; however, the objectives for the qualitative work are less clear. What were the specific objectives of the qualitative work and how did this relate to informing the development of the intervention?

Is the study design appropriate for the research question?

- Yes, the outcomes of the feasibility study are designed to measure outcomes relating to feasibility and acceptability of delivering the intervention and the design of a RCT to test the intervention.

Are sufficient details of the methods provided to allow replication by others?
The methods are clearly presented, below are some points for clarification:

- Although the manuscript predominantly focuses on the feasibility study, it would be helpful to have more information about the intervention development phase. Other than identifying topics for the intervention sessions, how will the qualitative work be used to inform the development of the intervention? The overall structure of the intervention appears to be predetermined, i.e. 6 sessions over 2 months; small groups with a facilitator; topics for each session and a workbook. How was this structure decided upon, why were 6 sessions chosen? How was PPI used at the development stage?

- There could be more details about the design of the qualitative study included without adding too much to the word count. For example: where will participants be recruited from; how many 1-1 interviews vs focus groups; who will conduct the interviews/focus groups; who will analyse the transcripts; what software will be used to manage the data? See Consolidated criteria for reporting qualitative research (COREQ) guidelines.

- How was minor stroke defined?

- One of the feasibility study objectives is “What are the most relevant outcome measures”, how will this be determined?

Are the datasets clearly presented in a useable and accessible format?

- This is a protocol; therefore, does not include datasets.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: stroke, qualitative research, feasibility studies

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 08 July 2020

https://doi.org/10.21956/amrcopenres.13981.r26513

Suzie Wang
School of Social Sciences, Leeds Beckett University, Leeds, UK

This is a well-written protocol aiming to address an important research gap on providing psychoeducational intervention for people who had TIA/minor stroke. This is also much needed in practice for the target population. I enjoyed reading the protocol. The main focus of this protocol is on the second phase- a feasibility randomised controlled trial. I have provided the following suggestions:

- I understand that the study is almost completed. Maybe for future reference, we could have a bit more information on the intervention used in the study (e.g., the content and order of the sessions).
- I do wonder how many participants were planned to be in the small group face to face intervention session. What might be the rationale for the decision regarding the numbers?
- It's great to see that people with aphasia (PWA) is not excluded in participating the study. Is there any tailoring made to ensure the intervention is suitable for PWAs?
- I missed some explanations on the 'usual care' in the setting.
- It would be great if we could see the participants feedback questionnaire in the protocol.
- I am slightly confused about the PPI in Phase 1, I assume members in this PPI did not participate in the Phase 1 focus group study.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: psychosocial interventions for stroke, stroke secondary prevention

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 08 Jul 2020

Eirini Kontou, University of Nottingham, Nottingham, UK

Thank you for your encouraging and helpful review. We agree that involving people with aphasia in stroke studies is important, however we did not foresee that people with TIA and minor stroke would experience communications difficulties that could affect their participation in the intervention. PPI members were consulted about the presentation and language in the participant workbooks. With regards to additional information on the intervention, please note that we have included in the OPTIMISM protocol the Template for Intervention Description and Replication (TIDieR) checklist v1.0. figshare. Online resource. https://doi.org/10.6084/m9.figshare.12473237.v1 We will follow your suggestion of including a description of usual care at the participating site in the results paper. We will consider including the feedback questionnaire responses of the participants who received the intervention when preparing future articles and presentations. This is not included in the protocol as it pertains detailed questions in relation to the content of the intervention. We would like to clarify that Phase 1 (Qualitative Study) invited participants who were interested to take part and agreed to sign a consent form. These were not the same as the PPI members or participants in Phase 2 (Feasibility Trial). Thank you for taking the time to review this protocol article.

Competing Interests: No competing interests were disclosed.

Reviewer Report 02 July 2020

https://doi.org/10.21956/amrcopenres.13981.r26509

Terry J. Quinn
Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, UK

- Dr Kontou and collaborators offer a protocol for their Stroke Association funded program, of work looking at a psychoeducational intervention following transient ischaemic attack (TIA).

- This seems a well-designed project in a field where more research is urgently needed.

- The protocol majors on phase II – a single centre pilot.

- As this is a protocol for a study that is now complete there is no value in suggesting changes to the method of the study (I didn't think changes were needed anyway). Rather, I will limit my comments to those aspects that perhaps need a bit more clarity in the description. I would hope this would be helpful to the team when they come to share their work as a scientific paper.

- The target population is TIA. The definition of TIA continues to evolve, and the working definition varies across centres depending on access to acute imaging. I think the team need to fully operationalise the TIA/minor stroke concept and if they are using a time-based, rather than tissue-based definition this needs to be justified. I accept that a time-based definition is still common in most of the UK NHS.

- As the study is now complete, it would be good to know more about the content of the intervention and its delivery. Perhaps this is the focus of an alternative paper.

- Usual care of TIA/minor stroke varies considerably, and it would be useful to know a little more about usual care in the setting of this single centre trial.

- The 'Research Aims' section outlines a series of secondary objectives that are not mentioned again in the 'Outcomes' section.

- Feasibility studies are often used to inform whether a full scale trial should be pursued. In this case it is useful to pre-specify some 'go' and 'no-go' criteria around recruitment etc. Assuming the team haven't already started data analysis, there would be opportunity to add these progression criteria to this protocol.

- General Health Questionnaire 30 contains items relating to depression, I wasn't sure why the Patient Health questionnaire 2 was also needed. If the PHQ2 is being used as an initial screen to determine need for the longer questionnaire, then there is some recent research to support this approach: Levis *et al.* (2020[1]).

- Could the feedback questionnaire be included in the protocol?

- I am assuming there will not be a separate statistical analysis plan publication. So, the authors could use the protocol to prespecify how they will handle situations of missing data e.g. fully or partially incomplete postal questionnaires.

- The description of the patient involvement seemed a bit vague. The research team have a great track record in involving stroke survivors in their research, so I would like to see more in this section.

- At times some of the text reads more like an ethics/R&D application, rather than a protocol describing a now complete trial. For example rather than outline the various authorities that protocol amendments will be sent to, for this final protocol paper, it would be useful to actually state if there were any protocol amendments and what they involved.

- There are many data sharing platforms for stroke and vascular cognitive impairment – once primary analyses are complete are the authors going to share data with any of these platforms?

References

1. Levis B, Sun Y, He C, Wu Y, et al.: Accuracy of the PHQ-2 Alone and in Combination With the PHQ-9 for Screening to Detect Major Depression. *JAMA*. 2020; **323** (22). Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Stroke, trials, methods

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 08 Jul 2020

Eirini Kontou, University of Nottingham, Nottingham, UK

Thank you for accepting to review this protocol and your helpful comments.

We are grateful for your suggestions regarding future publications. We will consider reporting the protocol amendments required during the trial, the detailed description of PPI involvement and the statistical analysis plan in a results paper.

We agree that the definition of TIA is an ongoing issue for studies in this area. As this is a

feasibility trial, we aimed to be as inclusive as possible and to recruit people with a diagnosis of TIA as confirmed in their hospital medical notes. In line with your suggestion, the definitions of TIA and minor stroke will be further clarified when designing a future study.

We appreciate that you have drawn our attention to the paper by Levis *et al.* (2020). The PHQ-2 was selected as a brief measure that could be used to screen people when diagnosed with TIA/minor stroke and at follow-up. We wanted to explore the acceptability of two different mood measures completed and returned by post.

The group feedback questionnaire was designed for the purpose of this study and included in the protocol. We would like to note that the final approved ethics/R&D protocol is also available here: Kontou *et al.* (2020): OPTIMISM Research Protocol v4.0 17.05.18. figshare. Online resource. https://doi.org/10.6084/m9.figshare.12472361.v1

Thank you once again for taking the time to review this article and your recommendations.

Competing Interests: No competing interests were disclosed.